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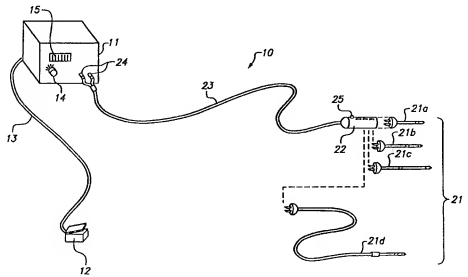


(57) Abstract

Methods and apparatus are provided for cauterizing predetermined volumes of biological tissue using a user selectable, or adjustable energy applicator including two or more electrodes (28, 29) having electrode parameters configured to cause cauterization of predetermined volumes when operated in a bipolar mode. The energy applicators (21) are employed with a control device (22) that couples the energy applicators to a power source (11), and includes circuitry (39) for interrupting activation of the energy applicator when the current between the two or more electrodes decreases more than a predetermined amount from the current sensed upon initial activation of the energy applicator.

METHODS AND APPARATUS FOR THERAPEUTIC CAUTERIZATION OF PREDETERMINED VOLUMES OF BIOLOGICAL TISSUE

Field Of The Invention

The present invention relates to apparatus and methods for in situ cauterization of biological tissue, and more particularly, for causing in situ necrosis of predetermined volumes of abnormal biological tissue, such as a malignant tumor.

Background Of The Invention

Apparatus and methods are known for inducing therapeutic hyperthermia in biological tissue by inductive, radiant, contact and joulean heating methods. Inductive methods, such as described in U.S. Patent Nos. 5,251,645 and 4,679,561, heat a volume of tissue located within a body cavity by passing high frequency electromagnetic radiation through tissue positioned between two external electrodes located near or in contact with the patient's skin. Heating is

to thermal gradient effects. For example, to heat a spherical volume of the tissue having a diameter of 2 cm to at least 60° C, a single heating element could be inserted along a diameter of the sphere. To raise the perimeter of the spherical volume to 60°C, the central regions must be raised to a higher temperature than the periphery to produce an adequate thermal gradient, as may be demonstrated using well-known thermal conduction equations.

A disadvantage of the often high thermal gradient across the spherical volume, depending on the tissue type and conductivity, is the unwanted evolution of steam, formation of eschar, and unwanted preferential heat transfer along the cannula support shaft, thereby detrimentally effecting healthy tissue outside the target region.

In order to overcome the foregoing limitations, dispersed contact heating methods also have been developed. For example, small spheres or wire segments of ferromagnetic alloys have been inserted into tumors in the brain and other tissue and heated to an auto-regulating temperature (i.e., the Curie temperature of the alloy) by an externally applied electromagnetic field. The resulting eddy current heating causes hyperthermia in the tissue immediately surrounding the small spheres or wire segments.

Yet another approach to therapeutic hyperthermia, referred to as "electrosurgery," utilizes heating produced by the flow of electrical current

such as described in U.S. Patent Nos. 5,069,223 and 4,140,109. A limitation of such previously known devices is the need for specially designed or dedicated control systems and/or power supplies capable of measuring the specific parameter of interest (e.g., temperature or electrical impedance). This requirement for specialized equipment often poses budgetary problems in health care institutions, thus limiting widespread acceptance of such devices.

Additionally, measurement of actual tissue impedance is complicated by the wide range of variation in the electrical properties of biological tissue depending on the fatty tissue content and vascularity of the tissue. Further, tissue temperature measurements may be influenced by the distance between the temperature sensor and the working surface of the device, often resulting in underestimation of temperatures for more distal regions of tissue. In particular, the use of electrosurgical heating methods can lead to tissue heating effects which may be several or tens of millimeters from the working surface, well beyond the range of a temperature sensor mounted near the working surface.

Another important limitation of previously known devices and methods is the necessity of an invasive procedure, following the biopsy procedure, to treat abnormal or diseased tissue. For example, breast tumors or other abnormal tissue masses may be first identified by palpation, radiography, thermography and/or ultrasonography. Once a tumor is detected, a

imaging techniques to facilitate accurate positioning of a tissue cauterization device.

It would also be desirable to provide methods and apparatus for treating tumors wherein an energy applicator could be tailored to the size and shape of the tumor, as quantified, for example, using tumor imaging techniques.

It would be desirable to provide methods and apparatus for treating abnormal tissue that include an automatic shut-off control, with suitable visual and/or audible indicators, that signal when therapy is complete, i.e., when a predetermined volume of tissue has been cauterized.

It would further be desirable to provide methods and apparatus for treating abnormal tissue that includes an expandable geometry that provides increased treatment surface area while in-situ but a relatively smaller insertion diameter, thereby reducing insertion trauma.

It yet further would be desirable to provide methods and apparatus for performing therapeutic cauterization of tissue using commonly available electrosurgical generators.

Summary Of The Invention

In view of the foregoing, it is an object of this invention to provide methods and apparatus, for use with existing tumor imaging techniques, capable of applying therapeutic hyperthermia, in situ, to any tumor which may be identified using minimally invasive procedures.

expandable geometry that provides increased treatment surface area while in-situ but a relatively smaller insertion diameter, thus reducing insertion trauma.

It is yet another object of the present invention to provide methods and apparatus for performing therapeutic cauterization of tissue using commonly available electrosurgical generators. In particular, devices constructed in accordance with the present invention may be designed to be compatible with previously known electrosurgical generators by accepting the available voltages and impedances of such generators, thereby eliminating the need for specialty generators.

In accordance with the present invention, apparatus is provided comprising two or more electrodes which are electrically isolated from one another, so that the only path for the flow of electrical current is through tissue contacting the electrodes. In accordance with the principles of the present invention, the apparatus permits selection of the electrode size and spacing, so that a predetermined volume of tissue may be heated to a temperature sufficient to cause irreversible necrosis. The two or more electrodes are disposed on either a rigid or flexible cannula or catheter.

Apparatus constructed in accordance with the invention allows application of therapeutic heating to a target tissue site promptly after a tissue biopsy procedure. When the tissue treatment applicator is used in conjunction with existing electrosurgical

electrode surface area during the energy application step, while reducing the diameter of the energy applicator during insertion.

In accordance with the methods of the present invention, patient physical discomfort and mental stress are reduced by: (1) the use of a local anesthetic applied to the site of the intended cauterization and (2) the completion of the therapeutic cauterization of tissue soon after completion of the biopsy procedure. In addition, the costs associated with medical treatment are reduced since therapy can be completed within the same time frame previously required for a biopsy procedure alone.

Brief Description Of The Drawings

Further features and advantages of the invention will become more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. 1 is a perspective view of apparatus constructed in accordance with the present invention, including various energy applicators, together with a power source;

FIGS. 2A and 2B are side views of an illustrative energy applicator and associated control device constructed in accordance with the present invention;

FIG. 3 is a partial sectional view of the distal tip of the energy applicator of FIGS. 2, showing

FIG. 11 is a view similar to that of FIG. 10 for an energy applicator having electrodes disposed over only a portion of the expandable members; and

FIG. 12 is a perspective view of yet another alternative embodiment of an energy applicator constructed in accordance with the present invention.

Detailed Description Of The Preferred Embodiments

Referring to FIG. 1, apparatus 10 includes power source 11 and therapeutic cauterization device 20 comprising a plurality of energy applicators 21a-21d and control device 22 that accepts and activates a selected one of the energy applicators. Control device 22 is coupled to power source 11 by cable 23 using connectors 24. Energy applicator 21 is energized by activation of switch 25 on control device 22, in conjunction with foot pedal 12. Foot pedal 12 is coupled to power source 11 by cable 13.

Power source 11 may be any one of a wide range of previously known and commercially available electrosurgical generators, such as the Valleylab Force 2 electrosurgical generator, sold by Valleylab Inc., Boulder, Colorado. Power source 11 includes at least power level (or voltage level) control 14 and power level (or voltage level) set point indicator 15, to allow a clinician to adjust the output of the power source to a set point level appropriate for the intended therapy. Alternatively, power source 11 may be a specially designed electrosurgical controller unit that incorporates the control and set point circuitry

having distal region 27 carrying two or more electrodes operable in a bipolar mode. The length of cannula 26 is dependent on the depth at which a target tissue site is located, typically, several to tens of centimeters from the external surface of a patient's body.

Proximal electrode 28 and distal electrode 29, which are electrically insulated from one another by insulated region 31, conduct radio-frequency current from power source 11 into tissue surrounding distal region 27 when activated. Energy applicator 21 connects to control device 22 (and is electrically coupled thereto) by insertion of plugs 32a and 32b extending from hub 33 into mating electrical receptacles 34a and 34b of control device 22.

With respect to FIG. 3, distal region 27 of energy applicator 21 is described in greater detail. Cannula 26 comprises shaft 40 comprising an electrically conducting material (e.g. metal or alloy) having sharpened distal tip 41. Distal tip 41 serves as distal electrode 29, and has a length of L_{DE} and diameter D_{DE}. A thin layer of electrical insulation 42 is disposed on the external surface of shaft 40 up to (but not including) distal electrode 29. A layer of electrically conductive material 43 is disposed on the layer of electrical insulation 42 to form annular proximal electrode 28, having outer diameter D_{PE}.

A further layer of electrical insulation 44 is disposed on electrically conductive material 43 for the length of cannula 26 (except for the length L_{PE} of electrically conductive material 43 exposed to form

comprises a thin-walled metal tube, such as stainless steel hypodermic tubing, having a wall thickness of 0.002 inch to 0.010 inch, and preferably 0.005 inch (0.13 mm) and a gauge size of about 2 to 20 French depending on the size of the tumor being treated. Electrically insulating materials 42 and 44 may comprise shrink tubing or be formed of a deposited insulating coating, such as Parylene, available from Specialty Coating Systems, Inc. Indianapolis, Indiana.

An illustrative energy applicator designed in accordance with the principles of the present invention may be characterized by the following set of dimensional parameters: L_{DE} = 6.2 mm and D_{DE} = 3.3 mm, L_{EE} = 1.9 mm, L_{PE} = 3.3 mm and D_{PE} = 3.7 mm, and an overall outside diameter of 3.8 mm.

Still referring to FIG. 2A, control device 22, which preferably serves as a reusable handle of the therapeutic cauterization device, is coupled to power supply 11 via cable 23. Control device 22 includes switch 25, lights 35a-35c, battery 36, current sensor 37 and limit circuit 38 coupled to control circuit 39. Wires 45a and 45b couple receptacles 34a and 34b to cable 23 via limit circuit 38, which may comprise, for example, a double pole switch. Switch 25, when depressed, causes lights 35a-35c to be individually illuminated, thereby indicating the status of the device, as described hereinbelow. A presterilized energy applicator is coupled to control device 22 by urging plugs 32a and 32b of the energy applicator into receptacles 34a and 34b of the control device.

Once the distal region of the energy applicator is properly positioned, the clinician depresses footpedal 12 (or another switch controlling activation of power source 11) to initiate application of radio-frequency voltage between proximal and distal electrodes 28 and 29, thereby causing current to flow through the tissue which effects the joulean heating of, and thereby, thermal necrosis of the tissue within a volume defined by electrode parameters L_{DE}, D_{DE}, L_{PE}, D_{PE} and L_{ES} of the energy applicator.

In accordance with the principles of the present invention, the preprogrammed logic within control circuit 39 monitors the current flow in wire 45b using current sensor 37, which communicates a sensed voltage to control circuit 39. When the current level sensed by current sensor 37 decreases from its initial value (e.g., obtained within a sample and hold period of about 100 msec following initial activation of the energy applicator) to a predetermined level (e.g., about one-fifth to one-tenth the initial current level), control circuit 39 causes double-pole switch 38 to be opened, thereby interrupting further application of current from power source 11. Simultaneously with causing the opening of limit circuit 38, control circuit 39 causes red light 35c to begin flashing, thus providing an indication to the clinician that treatment is complete. Control device 22 in addition may activate an audible indicator when red light 35c is illuminated.

However, as described hereinabove, the exposed electrode areas for any particular energy applicator may vary over a wide range, depending on the size of the target tissue volume to be cauterized and the characteristics of the target tissue. Accordingly, each energy applicator 21 may be supplied with a recommended set of power or voltage settings with which that energy applicator may be used with selected commercially available power sources.

Alternatively, power control circuitry that maintains the time-averaged power and/or current application below a limit value corresponding to the selected electrode parameters can be incorporated into control device 22. If both time-averaged power and current are being controlled, then a limit value may be applied for each of the time-averaged power and current application. In the illustrative embodiment of FIG. 2B, a predetermined limit value may be set within the power control device 22 based on "coding" or identifying circuit element 83 (e.g., a resistor or capacitor) contained within energy applicator 21. In FIG. 2B, in which elements of the embodiment of FIG. 2A are indicated by like reference numerals, "coding" or identifying circuit element 83 is connected to plugs 32a and 32c via leads 84 and 85, respectively.

Still referring to FIG. 2B, energy applicator 21 is coupled to control device 22 by inserting plugs 32a, 32b and 32c into receptacles 34a, 34b and 34c, respectively. Upon initial insertion, control circuit 86 measures a value of a parameter of circuit element

between the electrodes along current flux lines 101 to effect Joulean heating in the tissue in accordance with Ohm's law (i.e., as the product of (current)^2 x (tissue impedance)).

As the load impedance of the tissue decreases below 100 ohms, the output voltage and power output of conventional power sources (such as the Valleylab Force 2) decrease monotonically to zero, until no power is output when there is no load impedance. Also, as the load impedance increases from 100 to 1000 ohms, the output power again decreases monotonically, approaching a ten-fold lower output level at a 1000 ohm load impedance. At this ten-fold lower level, the power output is insufficient to raise the tissue temperature in the cauterization zone around the electrodes to a level that will result in irreversible necrosis of the tissue.

The impedance of most biological tissue increases when it is cauterized because of a change in the distribution of electrically conducting cellular fluids and an increase in the cellular membrane/fluid interface impedance. Accordingly, once a sufficient volume of tissue located between the electrodes of the energy applicator becomes cauterized, the current flow is restricted and current sensor 37 will detect a decrease in current level. When this decrease in current level (as sensed by current sensor 37) is detected by control circuit 39 (or control circuit 86 of the embodiment of FIG. 2B), the control circuit in

lobe centered on each electrode) and a mid-region of incomplete cauterization between the two lobes. This is because current density is too low in the mid-region to provide effective cauterization of the tissue.

As shown in FIGS. 5B and 5C, cauterization zone 111 tends to become more spherical as interelectrode spacing L_{ES} decreases. As the interelectrode spacing decreases and the cauterization zone becomes more spherical, electrode parameters L_{DE}, L_{DE}, D_{DE} and D_{DE} increasingly dictate the size of the cauterization zone relative to the effect of interelectrode spacing.

In accordance with the principles of the invention, in one embodiment of the therapeutic cauterization device, a plurality of energy applicators 21a-21d are provided, each having different electrode parameters L_{DE}, L_{DE}, D_{DE}, D_{DE} and L_{ES} that are established at the time of manufacture to effect the complete cauterization of different predetermined volumes 111. For example, in FIGS. 5A-5C, each distal region 27 of the respective energy applicators 21a-21c is constructed to treat a specified predetermined volume 111. Accordingly, the clinician may select an energy applicator to treat a tumor having a size and shape that has been determined by the clinician using suitable tumor imaging techniques (e.g., using radiography and/or ultrasonography methods).

In an alternative embodiment of the apparatus of the present invention, the energy applicator may be designed so that electrode parameters L_{DE}, L_{DE} and L_{ES} may

Such studies have revealed that, within one to two seconds after power application, only fractional volume 110 (see FIG. 4) of tissue is cauterized, located between the proximal edge of the distal electrode 29 and the distal edge of proximal electrode 28. If therapy were terminated at this point in time, volume 111 would not be completely cauterized, thus leaving some diseased or abnormal biological tissue untreated. By contrast, if a temperature sensor were positioned within volume 110, as suggested by some previously known devices, the temperature measurement would incorrectly indicate that the target tissue had reached the preselected temperature level when, in fact, only a fraction of the total desired treatment volume had reached a temperature sufficient for necrosis.

The foregoing studies have also demonstrated how the shape of the cauterization zone changes as a function of the electrode parameters and time, as shown in FIG. 6. In particular, the cauterization zone thickness and length are affected by the interelectrode spacing and the duration of time that energy is applied to the site. As will be apparent from FIG. 6, the length of the cauterization zone is effected more by the interelectrode spacing and the time duration than is the thickness of the cauterization zone. The length of the cauterization zone, as discussed above, is more sensitive to the interelectrode spacing, so that as the interelectrode spacing increases, up to the point at

Electrodes 52a-52c may of the thin film type, so that a selected one of proximal electrodes 52a-52c may be energized in conjunction with distal electrode 51. The lengths of proximal electrodes 52a-52c, as well as the lengths of insulating regions 54a-54c, may vary along the length of cannula 53, so that for each one of proximal electrodes 52a-52c energized in combination with distal electrode 51 for a specified time, a corresponding predetermined volume of tissue is cauterized.

For instance, after determining the size and shape of a region of abnormal tissue, a clinician could consult a table similar to FIG. 6 that provides length and thickness of the cauterized zone as a function of the proximal electrode. The clinician then activates a desired proximal electrode, using a selector switch on the control device (not shown), to cauterize the region of abnormal tissue. Alternatively, or in addition, more than one of proximal electrodes 52a-52c may be energized in combination with distal electrode 51.

Referring now to FIGS. 8A and 8B, a yet further alternative embodiment is described in which energy applicator 60 includes tubular shaft 61 having lumen 62. Distal edge 63 of tubular shaft 61 preferably includes bevel 64 to facilitate introduction and advancement of the energy applicator into biological tissue 120, and includes an exposed region forming distal electrode 65. Energy applicator is otherwise similar in construction to energy applicators 21 of FIGS. 2, and includes proximal electrode 66 and

welding, brazing or adhesive bonding, as appropriate to the materials of construction. By way of example, shaft 152 and trocar tip member 154 may be manufactured using biocompatible metals such as stainless steel, titanium or nickel-based alloys. Expandable members 160 and 170 are located at the distal and proximal ends, respectively, of working end 150, and may be formed from an elastomeric material such as polyurethane or polyethylene teraphthalate.

A portion or all of the outer surfaces of distal and proximal expandable members 160 and 170 are covered with electrically conducting layers, such as films of stainless steel, silver, gold or other biocompatible metal or alloy, that form electrodes 162 and 172, respectively. In FIG. 9B, electrodes 162 and 172 illustratively cover only a portion of the circumference of expandable members 160 and 170.

Locking collars 158a and 158b are positioned at the proximal and distal ends, respectively, of expandable member 160 to provide a fluid tight seal between expandable member 160 and shaft 152. Likewise, locking collars 168a and 168b are positioned at the proximal and distal ends, respectively, of expandable member 170 to provide a fluid tight seal between expandable member 170 and shaft 152. Distal hole 178 and proximal hole 182 allow fluid communication between lumen 151 of shaft 152 and the annular spaces formed between shaft 152 and expandable members 160 and 170.

Electrically insulated lead wires 180 and 184 are brought into electrical communication with the

distal electrode 162 and proximal electrode 172, with expandable members 160 and 170 being inflated. Working end 150 is first positioned in tissue 100 with distal electrode 162 and proximal electrode 172 in the unexpanded (i.e., minimum diameter) configuration, so as to minimize trauma to healthy tissue during the insertion step.

Once the proximal and distal electrodes are positioned relative to target tissue 192, as confirmed, for example, by fluoroscopy, radiography, ultrasonography or vectoring of a device based on previous mapping of target tissue (e.g., using computer aided tomography, magnetic resonance imaging and/or ultrasonography), expandable members 160 and 170 are inflated using suitable pressurizing fluid 190, such as sterile water or isotonic saline, to achieve the enlarged electrode shapes depicted in FIG. 10.

Once electrodes 162 and 172 are positioned with respect to target tissue 192 and inflated to expanded diameter D_{EE}, a high frequency voltage may be applied between plugs 32a and 32b at the proximal and of the energy applicator using the control device described hereinabove. Upon the application of an appropriate high frequency voltage to leads 180 and 184, current flows through tissue 100 located between electrodes 162 and 172, illustrated by current flux lines 101.

According to the selected sizes and spacing of electrodes 162 and 172 and the applied voltage and duration of energy application, a predefined volume of

Referring now to FIGS. 9B and 11, an embodiment of working end 150 is described in which proximal electrode 172 and distal electrode 162 only cover a portion of expandable members 170 and 160, respectively. In all other regards, this embodiment is similar to that of FIGS. 9A and 10 described hereinabove. The embodiment of FIG. 9B is particularly useful in treating target tissue 192 (e.g., tumor) that is adjacent to the working end of the energy applicator, but not pierced by the working end as in FIG. 10. This arrangement may be preferred in some treatment situations to avoid iatrogenic metastases that might otherwise occur when the vascular network within malignant tissue is disrupted (e.g., if the trocar tip pierced the tumor).

In FIG. 11, working end 150 is positioned adjacent to target tissue 192, the proximal and distal electrodes are expanded, and voltage is applied between the electrodes, thereby causing current to flow in the localized region defined by current flux lines 101. According to the selected sizes and spacing of electrodes 162 and 172 and the applied voltage and duration of energy application, predefined volume of tissue 113 is cauterized due to the attainment of a current density in volume 113 sufficient to cause heating to above about 60° to 70° C, resulting in irreversible necrosis of tissue throughout volume 113 (including target tissue 192).

The use of electrodes that cover only a portion of the expandable members allows a predefined

significant electrical impedance at the electrode/tissue interface.

Moreover, the preferred use of water or isotonic saline as the pressurizing fluid serves to moderate temperatures at the electrode/tissue interface, thereby further reducing localized tissue desiccation and/or water vapor generation at the electrode/tissue interface. Through the use of expandable electrodes, the diameter of the energy application may be maintained as small and atraumatic as possible, thereby allowing the use of the present invention in a wide range of applications, including office-based procedures, with little scarring and discomfort to the patient and reduced risk of iatrogenic injury to the patient.

With respect to FIG. 12, yet another embodiment of the energy applicator of the present invention is described. In this embodiment, the shaft of energy applicator 21e is divided into three distinct regions. The distal-most region comprises working end 150 as described hereinabove with respect to FIGS. 9, and may incorporate rigid shaft member 152 (e.g., stainless steel Type 304) and electrodes 162 and 172 disposed on expandable members 160 and 170, respectively. Flexible segment 206 is positioned between working end 150 and rigid support shaft 208. Support shaft 208 is, in turn, affixed to hub 194, which couples to control device 22. Hub 194 preferably includes mechanical actuation slider 196, which may be

It will be understood that the foregoing is merely illustrative of the apparatus and methods of the present invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the claimed invention.

3. The kit as defined in claim 2, wherein for at least one of the plurality of energy applicators the distal electrode comprises a sharpened end of a solid cylindrical shaft.

4. The kit as defined in claim 2, wherein for at least one of the plurality of energy applicators the distal electrode comprises a hollow cylindrical shaft.

5. The kit as defined in claim 4 wherein for at least one of the plurality of energy applicators the distal electrode has a sharpened edge to facilitate introduction and advancement of the energy applicator into biological tissue.

6. The kit as defined in claim 4, wherein for at least one of the plurality of energy applicators an extraction device is located within the hollow cylindrical shaft, the extraction device being operable in combination with the energy applicator to sever a sample of biological tissue.

7. The kit as defined in claim 1 wherein the handle further comprises:

a current detector that measures a current flowing between the proximal and distal electrodes during activation of the energy applicator, the current detector measuring a first current value upon initial activation of the energy applicator and a second

12. The kit as defined in claim 1, wherein the control circuitry further comprises:

a timer that measures a preset period of time from activation of the energy applicator; and

circuitry that terminates supply of power to the energy applicator when said preset period elapses.

13. The kit as defined in claim 1, wherein the control circuitry further comprises:

a coding element disposed within an energy applicator; and

circuitry that measures a value of a parameter of the coding element to determine an upper power or current limit value corresponding to a maximum power density or current density to be applied to the biological tissue.

14. The kit as defined in claim 1, wherein at least one of the plurality of energy applicators further comprises an expandable member having a contracted diameter for insertion into the biological tissue and an expanded diameter, one of the proximal electrode and distal electrode disposed on the expandable member.

15. The kit as defined in claim 14 wherein the energy applicator further comprises means for injecting a pressurizing fluid into the expandable member, the pressurizing fluid moderating the

the supply of electric current between the first and second electrodes.

17. The apparatus as defined in claim 16, wherein the first and second electrodes are coaxially aligned.

18. The apparatus as defined in claim 16 wherein the shaft includes a lumen.

19. The apparatus as defined in claim 16 wherein the shaft has a sharpened tip to facilitate introduction and advancement of the energy applicator into biological tissue.

20. The apparatus as defined in claim 18, further comprising a biopsy cannula disposed within the lumen, the biopsy cannula operable to sever a sample of biological tissue.

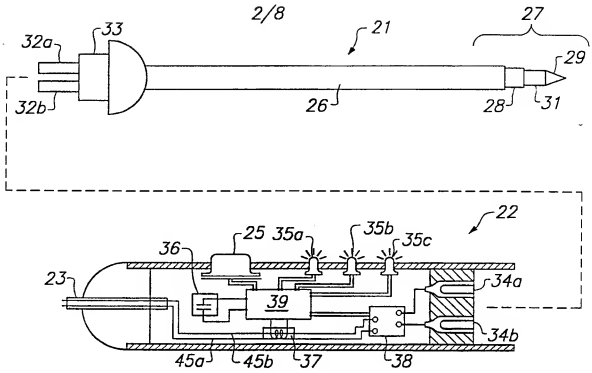
21. The apparatus as defined in claim 16, wherein the control circuitry comprises:

a current detector that measures a current level between the first and second electrodes, the current detector measuring an initial current value upon activation of the energy applicator and a present current value following initial activation of the energy applicator; and

circuitry for terminating the supply of power to the energy applicator when the present current value

26. The apparatus as defined in claim 16, wherein at least one of the energy applicators further comprises an expandable member having a contracted diameter for insertion into the biological tissue and an expanded diameter, the first electrode disposed on the expandable member.

27. The apparatus as defined in claim 26 wherein the energy applicator further comprises means for injecting a pressurizing fluid into the expandable member, the pressurizing fluid moderating the temperature of the first electrode.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32b
26
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38

FIG. 2A

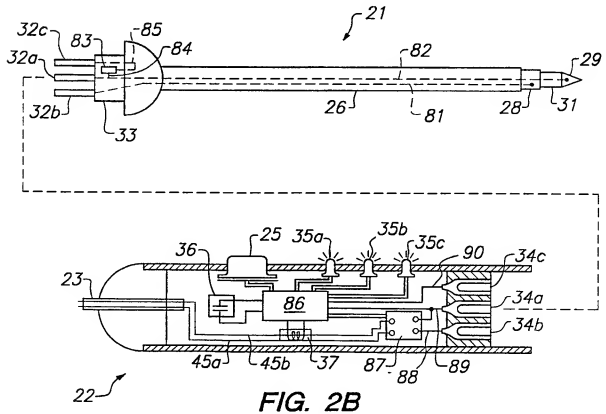
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FIG. 2B

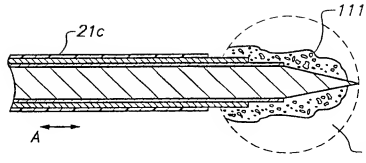

FIG. 5A

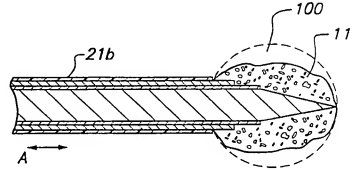

FIG. 5B

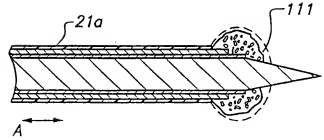

FIG. 5C

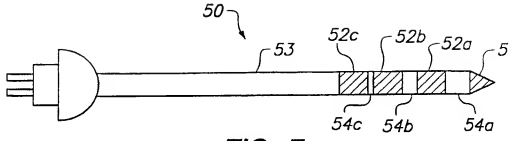

FIG. 7

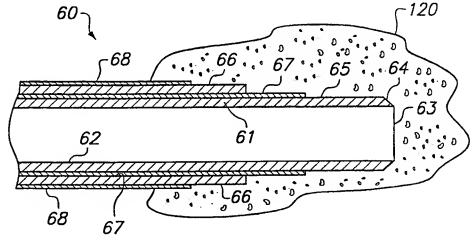

FIG. 8A

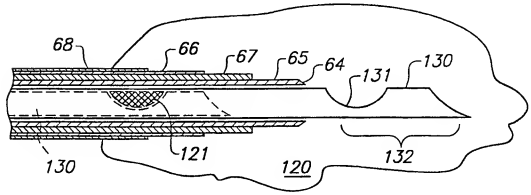

FIG. 8B

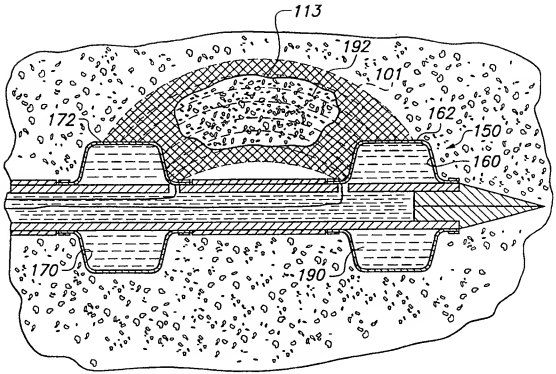
113
192
101
172
162
150
160
170
190

FIG. 11

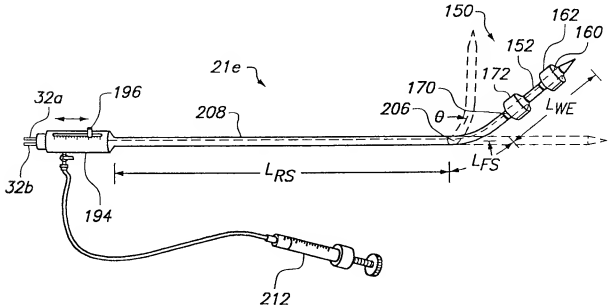
150
162
160
152
21e
172
32a
196
170
208
206
θ
LWE
LRS
LFS
32b
194
212

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/13414

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,599,345 A(EDWARDS et al.) 04 February 1997, entire document.	7, 8, 21, 22
Y	US 5,383,874 A (JACKSON et al.) 24 January 1995, entire document.	13, 25
Y	US 5,117,828 A (METZGER et al.) 06 February 1992, entire document.	11